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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,066	08/23/2001	Hisakazu Katsuki	KATSUKI=1	8579

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EXAMINER	
EVANS, CHARESSE L	
ART UNIT	PAPER NUMBER
1615	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/914,066	KATSUKI, HISAKAZU	
	Examiner	Art Unit	
	Charesse L. Evans	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6-14,16,19 and 20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *6-14,16,19 and 20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Action Summary

Acknowledgement is made of the receipt of applicant's Reply to Final Office Action, Amendment and Remarks, Petition for Extension of Time, filed November 18, 2003 and Request for Continued Examination, filed December 18, 2003.

Claims 6-14, 16 and 19-20 are pending in this action.

Priority

This application is a national stage entry of PCT/JP00/00862, International filing date February 16, 2000.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 19 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Lacy et al (US 6,096,338). The independent claims are directed to a composition composed of a soft capsule filled with a formulation of a dihydrobenzofuran derivative in soybean oil, said fill solution being substantially free of any other components.

Lacy et al (US 6,096,338) teaches a delivery system for hydrophobic drugs in which the carrier comprises a digestible oil and a surfactant (column 4, lines 1-7). The preferred digestible oils include vegetable oils such as soybean oil (column 9, lines 35-56). Among the hydrophobic drugs which may be formulated in accordance with the disclosed invention, probucol, is indicated (column 13, line 4). The concentration of drug in the final formulation will be that which is required to provide the desired therapeutic effect from the drug concerned, but will generally lie in the range of 0.1% to 50% by weight (column 13, lines 25-29). The compositions for oral administration

may be solid, liquid or semi-solid such as liquid oral dosage forms filled into hard or soft gelatin capsules (column 14, lines 52-58).

The examiner reads the limitation "substantially free" as allowing the presence of other components within the claimed soybean and active (probucol) solution. Therefore, the fact that the Lacy invention allows the presence of a surfactant within its soybean and active solution does not mitigate the applicability the reference to the cited claims.

Lacy teaches every aspect of claims 19 and 20, thus anticipating the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each

claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-14, 16 and 19-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lacy et (US 6,096,338) in view of Amey et al (US 6,080,426). The 102(e) discussion is applied as above. The capsule of lacy does not expressly teach that the soft gelatin capsules contain sorbitol. However, Amey supplies this deficiency by teaching that it is well known within the pharmaceutical dosage units arts to include components such as sorbitol within a gelatin based capsule shell (column 3, lines 30).

While the reference does not expressly teach applicant's claimed percent weight of sorbitol or gelatin, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

Regarding the limitation that the shell thickness is from $28x10^{-3}$ inches to $40x10^{-3}$ inches, the examiner determines that this limitation fails to impart a patentable distinction upon the claimed invention. It is the position of the examiner that these are limitations that would be routinely determined by one of ordinary skill in the art,

through minimal experimentation, as being suitable, absent the presentation of some unusual and/ or unexpected results. The results must be those that accrue from the specific limitations.

The Amey reference does not expressly state that the capsules are soft. However, there is a suggestion that the capsules shells may indeed present as soft dosage forms due to the presence of the relative amounts of plasticizer as well as lubricant and extender (column 3, lines 29-55). Accordingly, it would be obvious to one of ordinary skill in the pharmaceutical arts to combine the teachings of Lacy with the teachings of Amey. The expectation would be that by manipulating factors such as adding sorbitol to the carrier capsule, enhanced solubility, thus enhanced bioavailability, is obtained of the active ingredient.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Charesse L. Evans whose telephone number is 571-272-0593. The examiner can normally be reached on Monday - Thursday 7:00a - 4:30p; Alternating Fridays 7:00a - 3:30p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 571-272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Charesse L. Evans
Examiner
Art Unit: 1615

April 13, 2004

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600